

AMENDED IN SENATE APRIL 21, 2003

SENATE BILL

No. 506

Introduced by Senator Sher

February 20, 2003

An act to amend Section 4053 of, *and to add Section 4053.5 to*, the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 506, as amended, Sher. Veterinary food-animal drug retailers, *wholesalers, and distributors.*

The Pharmacy Law, *administered by the California State Board of Pharmacy in the Department of Consumer Affairs*, makes it unlawful for any person other than a pharmacist to compound or dispense a dangerous drug or device, or to compound or dispense a prescription. Existing law provides exemptions from this prohibition for specified persons, including a veterinary food-animal drug retailer under certain circumstances.

This bill would prohibit a veterinary food-animal drug retailer from applying for an exemption to distribute oral or injectable antibiotics.

Existing law prohibits a person from selling a livestock drug in the state without a registration certificate from the Department of Food and Agriculture to sell livestock drugs.

This bill would require a wholesaler or distributor of specified veterinary antibiotics or products containing antibiotics to provide the board with an annual report containing certain information for each sale or distribution. The bill would require the board to prepare a report compiling this information and to make it available on its Web site. The bill would authorize the board to collect fees from wholesalers and distributors sufficient to recover its costs under the bill. The bill would

create the Veterinary Antibiotics Control Fund in the State Treasury and the money from the fees would be deposited in the fund and be available for the administrative and enforcement costs of the board upon appropriation by the Legislature.

Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4053 of the Business and Professions
2 Code is amended to read:

3 4053. (a) Subdivision (a) of Section 4051 shall not apply to
4 a manufacturer, veterinary food-animal drug retailer, or
5 wholesaler if the board shall find that sufficient, qualified
6 supervision is employed by the manufacturer, veterinary
7 food-animal drug retailer, or wholesaler to adequately safeguard
8 and protect the public health, nor shall Section 4051 apply to any
9 laboratory licensed under Section 351 of Title III of the Public
10 Health Service Act (Public Law 78-410).

11 (b) An individual employed by a manufacturer, veterinary
12 food-animal drug retailer, or wholesaler may apply for an
13 exemption from Section 4051. In order to obtain and maintain that
14 exemption, the individual shall meet the following requirements:

15 (1) He or she shall be a high school graduate or possess a
16 general education development equivalent.

17 (2) He or she shall have a minimum of one year of paid work
18 experience related to the distribution or dispensing of dangerous
19 drugs or dangerous devices or meet all of the prerequisites to take
20 the examination required for licensure as a pharmacist by the
21 board.

22 (3) He or she shall complete a training program approved by the
23 board that, at a minimum, addresses each of the following subjects:



1 (A) Knowledge and understanding of state and federal law
2 relating to the distribution of dangerous drugs and dangerous
3 devices.

4 (B) Knowledge and understanding of state and federal law
5 relating to the distribution of controlled substances.

6 (C) Knowledge and understanding of quality control systems.

7 (D) Knowledge and understanding of the United States
8 Pharmacopoeia standards relating to the safe storage and handling
9 of drugs.

10 (E) Knowledge and understanding of prescription
11 terminology, abbreviations, dosages and format.

12 (4) The board may, by regulation, require training programs to
13 include additional material.

14 (5) The board may, by regulation, require training programs to
15 include additional material.

16 (6) The board shall not issue a certificate of exemption until the
17 applicant provides proof of completion of the required training to
18 the board.

19 (c) The manufacturer, veterinary food-animal drug retailer, or
20 wholesaler shall not operate without a pharmacist or an individual
21 in possession of a certificate of exemption on its premises.

22 (d) Only a pharmacist or an individual in possession of a
23 certificate of exemption shall prepare and affix the label to
24 veterinary food-animal drugs.

25 (e) Notwithstanding any other provision of law, a veterinary
26 food-animal drug retailer may not apply for an exemption to
27 distribute injectable or oral antibiotics.

28 *SEC. 2. Section 4053.5 is added to the Business and*
29 *Professions Code, to read:*

30 *4053.5. (a) This section applies to wholesalers or*
31 *distributors who sell or distribute any of the following for use on*
32 *livestock, poultry, or other food-producing animals:*

33 *(1) Prescription antibiotics.*

34 *(2) Over-the-counter oral or injectable antibiotics.*

35 *(3) Feed containing antibiotics.*

36 *(b) A wholesaler or distributor shall provide an annual report,*
37 *on a form prescribed by the board, containing, for each sale or*
38 *distribution of an item described in subdivision (a), information*
39 *that includes, but is not limited to, all of the following, on a county*
40 *specific basis:*

- 1 (1) *The identity of the antibiotic, including its generic and trade*
2 *name.*
- 3 (2) *The market status of the antibiotic.*
- 4 (3) *The target animal species and age group that the antibiotic*
5 *will be used for.*
- 6 (4) *The claimed use of the antibiotic.*
- 7 (5) *The dosage form for the antibiotic.*
- 8 (6) *Any other information that the board deems appropriate.*
- 9 (c) *The board shall do all of the following:*
- 10 (1) *Create a form upon which reports required by subdivision*
11 *(b) shall be prepared.*
- 12 (2) *Not less than annually, prepare a report compiling the*
13 *information collected pursuant to subdivision (b). The report shall*
14 *be made available to the public on the board's Web site.*
- 15 (3) *If disclosure of data for an individual company would*
16 *reveal legitimate confidential business information, aggregate the*
17 *data so as to avoid disclosure of that confidential business*
18 *information, where feasible.*
- 19 (d) *The board may impose fees on wholesalers and distributors*
20 *subject to this section. The fees may not exceed the amount of the*
21 *board's costs of collecting, analyzing, and disseminating*
22 *information pursuant to this section. The board shall deposit the*
23 *fee money received in the Veterinary Antibiotic Control Fund.*
- 24 (e) *The Veterinary Antibiotic Control Fund is hereby created in*
25 *the State Treasury. The board shall report to the Controller at the*
26 *beginning of each calendar month, for the month proceeding, the*
27 *amount and source of all revenue received by it pursuant to this*
28 *section, and shall pay the entire amount to the Treasurer for*
29 *deposit into the fund. Moneys in the fund shall be available to the*
30 *board to administer and enforce this section upon appropriation*
31 *by the Legislature.*
- 32 SEC. 3. No reimbursement is required by this act pursuant to
33 Section 6 of Article XIII B of the California Constitution because
34 the only costs that may be incurred by a local agency or school
35 district will be incurred because this act creates a new crime or
36 infraction, eliminates a crime or infraction, or changes the penalty
37 for a crime or infraction, within the meaning of Section 17556 of
38 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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